

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF FLORIDA

CASE NO. \_\_\_\_\_

UNITED STATES OF AMERICA

Plaintiff,

vs.

DR. CHAD LIVDAHL, N.D., DR. ZARAH  
KARIM, N.D., TOXIN RESEARCH  
INTERNATIONAL, INC., POWDERZ,  
INC., THE COSMETIC PHARMACY,  
INC., and Z SPA, INC.,

Defendants.

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**MEMORANDUM OF LAW IN SUPPORT OF UNITED STATES EMERGENCY  
MOTION FOR TEMPORARY RESTRAINING ORDER,  
PRELIMINARY AND PERMANENT INJUNCTION**

**I. Introduction:**

Plaintiff, the United States of America, by and through the undersigned Assistant United States Attorney, files this memorandum of law in support of its motion for a temporary restraining order, preliminary and permanent injunction pursuant to 21 U.S.C. § 332(a), and 18 U.S.C. § 1345. This lawsuit seeks to enjoin the defendants, Dr. Chad Livdahl, N.D., individually, Dr. Zarah Karim, N.D., individually, Toxin Research International, Inc., Powderz Inc., and The Cosmetic Pharmacy, Inc., from continuing to violate the Federal Food, Drug and Cosmetic Act (“FDCA”), 21 U.S.C. § 331(a), by causing the introduction or delivery for introduction into interstate commerce of a drug, as defined in 21 U.S.C. § 321(g)(1), which is

misbranded, as defined in 21 U.S.C. § 352(f)(1), in that the Botulinum Toxin Type A which was delivered in interstate commerce did not bear adequate directions for use.<sup>1</sup>

Defendants also are subject to 18 U.S.C. § 1345, in that defendants represented to federal Food and Drug Administration investigators that they did not sell their product to physicians or entities engaged in human, non-research use. However, defendants' actions and sales subsequent to their statement to the FDA inspectors demonstrate the contrary. Defendants have thus violated 18 U.S.C. §§ 371 and 1001, and thus must be enjoined under 18 U.S.C. § 1345. Because the defendants' activities are illegal and create a substantial risk to the public health, the United States asks this Court to expeditiously grant the relief sought in the accompanying proposed Order.

## **II. Standard for Injunctive Relief**

The traditional injunction requirements are (1) substantial likelihood of success on the merits; (2) irreparable harm; (3) inadequacy of other remedies at law; and (4) the public interest for the issuance of a preliminary injunction. Four Seasons Motels v. Consoccia Barr, S.A., 320 F.3d 1205, 1210 (11<sup>th</sup> Cir. 2003); Johnson & Johnson Vision Care, Inc. v. 1-800 Contacts, Inc., 299 F.3d 1242, 1246 (11<sup>th</sup> Cir. 2002). In practical application, those requirements are inter-related. For example, the quantum of proof necessary for success on the merits depends upon the showing of irreparable harm; thus, where proof of irreparable harm is strong, a lesser showing of probable success on the merits is required. 11A Wright and Miller Federal Practice and Procedure ¶ 2948.3 (1995); Palmer v. Braun, 287 F.3d 1325, 1329 (11<sup>th</sup> Cir. 2002); Morton v.

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<sup>1</sup> Throughout defendants' promotion materials, invoices, consent forms, and product labeling, TRI uses the terms "Botulinum Toxin Type A" and "Botulinum NeuroToxin Type A," interchangeably. (Affidavit, ¶7, n.2).

City of St. Augustin, 272 F.3d 1318, 1326 (11<sup>th</sup> Cir. 2001); Suntrust Bank v. Houghton Mifflin Co., 268 F.3d 1257, 1265 (11<sup>th</sup> Cir. 2001); Crochet v. Housing Authority of City of Tampa, 37 F.3d 607, 611 (11<sup>th</sup> Cir. 1994); Church v. City of Huntsville, 30 F.3d 1332, 1342 (11<sup>th</sup> Cir. 1994).

However, where as here, a statute authorizes injunctive relief, the government need not show irreparable injury to the public.<sup>2</sup> Gresham v. Windrush Partners, Ltd., 730 F. 2d 1417, 1424 (11<sup>th</sup> Cir. 1984); Atchison, Topeka and Santa Fe Ry. CO., v. Lennen, 640 F. 2d 255, 260 (10<sup>th</sup> Cir. 1981). Instead, the government is entitled to an injunction if it establishes that the statute pursuant to which suit has been brought has been violated and there is a cognizable danger of recurrent violations. United States v. Hayes Int'l Corp., 415 F.2d. 1038, 1045 (5<sup>th</sup> Cir. 1969). The probability of future violations may be inferred from past unlawful conduct. U.S. by Clark v. Gramer, 418 F.2d 692, 695 (5<sup>th</sup> Cir. 1969; United States v. W.T. Grant Co., 345 U.S. 629, 633 (1953). The United States need only adduce “probable cause” or “reasonable cause” in support of the merits of its claim. See FTC v. World Travel Vacation Brokers, Inc., 861 F. 2d 1020, 1028-29 (7<sup>th</sup> Cir. 1998) (stating that federal statute’s purpose in giving FTC specific authority to seek injunctive relief sought to “protect the American consumer from [prohibited] activity as quickly as possible, and was to relieve the Commission from the “requirements imposed by the traditional equity standard which the common law applies to private litigations”). That reasoning applies to the case before this Court. Thus, a federal statute authorizing

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<sup>2</sup>21 U.S.C. § 332 specifically grants federal courts injunctive power to restrain violations of the Federal Food and Drug Cosmetic Act, 21 U.S.C. §331. Similarly, under the Fraud Injunction Statute, 18 U.S.C. § 1345, the United States is explicitly authorized to commence a civil action in any Federal Court to enjoin violations contained within, and explicitly grants the court the power to “enter such a restraining order or prohibition, or take such other action, as is warranted to prevent a continuing and substantial injury to the United States.” 18 U.S.C. § 1345(a)(3)(b).

injunctive relief supersedes the traditional requirements for the issuance of an injunction, and the traditional burden of proof is lower and the balancing of equities is not applicable. As the court in World Bank coined it, the standard is the “public interest” approach. Id. at 1028.

The emergency injunctive relief is necessary in this matter because the potential for future harm is great. As set forth in Agent Leeds and Agent Korb’s affidavits, the United States’ Complaint, and below, the defendants’ record of non-compliance with the FDCA is well documented. Indeed, as late as December 22, 2004, even following a warning in October from an FDA inspector not to sell Botulinum Neurotoxin Type A for human use, and the execution of a federal search warrant on December 4, 2004, defendants have continued to market their product to physicians knowing that their only plausible use of the product would be on humans. Moreover, defendants’ continuing plans for seminars and future treatments, as well as an active website and phone number for ordering Botulinum Toxin Type A, leave little doubt that the defendants will continue to operate in violation of the law. Hence, this Court should act to stop defendants’ ongoing violations that could cause serious injury to consumers.

### **III. The Defendants Have Violated the Federal Food and Drug Cosmetic Act**

#### **A. Parameters of the FDCA:**

The Federal Food and Drug Cosmetic Act, Title 21, United States Code, Section 331(a) prohibits “[t]he introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded.” Title 21, United States Code, Section 321(g)(1), in turn, defines a “drug,” in relevant part, as “. . . (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of

man or other animals . . . .” Section 352(f) of Title 21, United States Code, provides that a drug shall be deemed to be “misbranded” “[u]nless its labeling bears (1) adequate directions for use . . . ,” among other defects. As it pertains to the definition of a “drug,”

The words intended uses . . . refer to the objective intent of the persons legally responsible for the labeling of drugs. The intent is determined by such persons’ expressions or may be shown by the circumstances surrounding the distribution of the article. . . . It may be shown by the circumstances that the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised. The intended uses of an article may change after it has been introduced into interstate commerce by its manufacturer . . . But if a manufacturer knows, or has knowledge of facts that would give him notice, that a drug introduced into interstate commerce by him is to be used for conditions, purposes, or uses other than the ones for which he offers it, he is required to provide adequate labeling for such a drug which accords with such other uses to which the article is to be put.

21 CFR 201.128 (emphasis added).

**B. Defendants’ Product is a “Drug” Delivered in Interstate Commerce, which is “Misbranded” under the FDCA:**

Defendants have subjected themselves to the provisions of the FDCA, and have clearly misbranded the Botulinum Toxin Type A. In an attempt to avoid being termed a “drug” under § 321(g)(1), defendants have littered their product and all promotions associated with it with the phrase, “For Research Purposes Only; Non Human Use Only.” For example, such “warnings” can be found throughout TRI’s website, specifically on the order form. (Affidavit of FDA Special Agent Susan J. Leeds, (“Affidavit”), ¶ 7). Similar phrases are found in TRI’s “Product Details’ for the Botulinum Toxin Type A. Id. The FDA Center for Drug Evaluation and Research (CDER) does not have a pending application for approval of a product or drug of any kind made or sponsored by any of the defendants in this matter, nor has FDA approved products or drugs of any kind made or sponsored by any of the defendants in this matter. (Affidavit, ¶ 3).

The principals of TRI (as well as Powderz and The Cosmetic Pharmacy), defendants Chad Livdahl and Zarah Karim, specifically told FDA investigators that their product was sent only to individuals conducted in non-human research, and thus they did not have to register an IND (Investigational New Drug) or an NDA (new Drug Application) with the FDA. (Affidavit, ¶ 13). However, the overwhelming evidence is that defendants intended to, and did market and distribute their product in interstate commerce as a drug; i.e. an article intended to affect the structure and/or function of the body of man. 21 U.S.C. § 321(g)(1)(C).<sup>3</sup>

When FDA Consumer Safety Officer (“CSO”) Randall Johnson conducted his investigation of TRI in October 2004, Dr. Karim did not respond to CSO Johnson’s question regarding whether the physicians purchasing the product were performing their research on humans, animals, or tissue cultures. (Affidavit, ¶14).<sup>4</sup> According to the Establishment

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<sup>3</sup>The Interstate Commerce prong of the FDCA, (much like the other elements of the FDCA), is clearly satisfied. "Interstate commerce" is defined as "commerce between any State or Territory and any place outside thereof." 21 U.S.C. § 321(b)(1). Thomas P. Toia, an employee of Advanced Integrated Medical Center, Inc., (“Advanced Integrated”), 1655 E. Oakland Park Boulevard, Fort Lauderdale, Florida, 33334, since September 2003, whose father was the owner of the center, was responsible for ordering medical supplies for the clinic, including, at the direction of doctors, drugs. He stated that on two to four occasions, he ordered vials of Botulinum Toxin Type A from TRI for Advanced Integrated by telephone, and received such orders through an interstate carrier, UPS. (Affidavit, ¶ 18). Additionally, FDA investigators executing the federal search warrant on TRI found copies of five (5) invoices in the FDA search of TRI, dated December 1 and 2, 2004, and completed order forms for TRI’s Botulinum Neurotoxin Type A reflecting sales to: Dr. Robert West at the Almos Heights Skin Clinic in San Antonio, Texas; Dr. Martha Gonzalez, Physician and Surgeon, Ventura California; Dr. Kreg Jenson, Physician and Surgeon, Oren Utah; and Dr. Herbert Smyczek, Newark, New Jersey. (Affidavit, ¶ 17g.). Also, Dr. Martin Blau, from New York and Dr. Herve Gentile from Texas, stated they purchased the product from TRI. (Affidavit, ¶¶ 20, 21).

<sup>4</sup>According to the EIR, FDA initiated the inspection upon receiving a complaint from a cosmetic surgeon in Tennessee, who advised the FDA he had been receiving literature from TRI which the doctor believed to be in furtherance of a fraudulent business scheme involving the sale of Botox. (Affidavit, ¶ 13).

Inspection Report, (“EIR”), Dr. Livdahl refused to allow the FDA to review customer distribution lists during the inspection, claiming confidentiality. (Id.).

A federal search of Advanced Integrated Medical Center on December 1, 2004, revealed a three page document from TRI, which included a Material Safety Data Sheet on Botulinum Neurotoxin Type A, as well as a document labeled “Product Details” on Botulinum Neurotoxin Type A.<sup>5</sup> (Affidavit, ¶7).<sup>6</sup> On December 4, 2004, the FDA participated in the service of a search warrant at the offices of TRI and Powderz, both found at 3280 Hemisphere Loop, Tucson, Arizona, 85706. (Affidavit, ¶ 8). Chad Livdahl is President and Chief Executive of TRI. He was a founding member of TRI’s Board of Directors. Dr. Livdahl is president of Powderz, and is the sole member of Powderz’ board of directors. Zahra Karim was a founding member of TRI’s Board of Directors. Dr. Karim is also Powderz’ registered agent. (Affidavit, ¶¶ 10, 11). OCI agents seized numerous marketing and registration materials relating to seminars held by Livdahl and Karim. These documents reflect Powderz conducted the seminars in July 2003 and October 2003, and prepared materials for another in September 2004. (Affidavit, ¶ 16).

Included in these materials were:

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<sup>5</sup> Throughout defendants’ promotional materials, invoices, consent forms, and product labeling, TRI uses the terms “Botulinum Toxin Type A” and “Botulinum NeuroToxin Type A,” interchangeably. (Affidavit, ¶7, n.2).

<sup>6</sup>At Advanced Integrated Medical Center, four individuals were afflicted with botulism on or about November 26, 2004. An employee, Bach, McComb, an osteopathic doctor, whose license was actually suspended on April 15, 2003, injected himself and three other victims with purported “Botox.” (Affidavit, ¶ 6). The Court should be aware, however, that the United States does not believe that the purported “Botox” used in this specific incident was TRI’s product. Rather, it is the United States’ belief that the purported “Botox” used to inject these four victims was a product manufactured by List Biological Laboratories, Inc. – a company not named in this lawsuit. However, notably, records do indicate sales of Botulinum Toxin Type A by TRI to Advanced Integrated on at least four separate occasions in 2004. (Affidavit, ¶ 18).

a. A registration brochure for the July 19-20, 2003, seminar, titled “The Physician’s Approach to Compounding for Aesthetic Enhancement ‘Hands-On’ Workshop and Demonstration,” which advertises a block of instruction from 3:00 p.m. to 4:00 p.m. on July 19, 2003 titled “Botulinum Toxin Type A,” and a block of instruction from 8:00 a.m. to 1:00 p.m. on July 20, 2003, called “Demo/Tutorial Course Botulinum toxin type A, Hyaluronic acid.” One of the presenters listed in the July 2003 brochure was Bach McComb, D.O., N.D., Ph.D.

b. Handwritten consent forms, titled “Botulinum Toxin Type A Consent Form and Cross Linked Hyaluronic Acid for Injection,” which appear to be signed by participants at the July seminar, and state as their purpose, “Educational Demonstration.” Several also include in the purpose statement the following: “This is not to be construed to be the practice of medicine.” The consent form lists possible side effects, to include: bruising, redness, droopy eyelid, double vision, pain, and need for more treatment; more or less effect than desired / lumpy appearance, and concludes with the statement, “I agree I have had the opportunity to ask questions.” On a majority of these signed forms, the sentence continues with, “. . . and am having this treatment voluntarily.” Also, blank, unexecuted copies of the handwritten consent form were also located and seized. A typewritten version of a consent form, called “Patient Informed Consent,” unsigned, was seized. It stated: “This consent form is intended to provide (Name) with the information needed to make an informed decision as to whether or not to undergo Botulinum Toxin Type A (AKA: Botox®, Dysport®, Botulinum Toxin) injection therapy for the treatment of wrinkles, forehead furrowing, frown lines, wrinkling around the eyes, and/or eyelid twitching.”

c. An agenda for the October 18, 2003, “Powderz Cosmetic Compounding” seminar, which included a 30-minute instruction block called “Botulinum Toxin Type A & Discussion.” Notably, a warning regarding Photography/Audio/Visual Taping Restrictions is included in this agenda which reads: “There is strictly no photography, audio, or visual taping allowed. Anyone found photographing or taping without authorization will be required to immediately surrender the film or tape, subject to expulsion, with no reimbursement or further recourse.”

d. Also, single-page disclaimers which appear to be signed by participants of this October 2003 seminar, which state, in part:

“Powderz disclaims any and all liability for injury or other damages resulting to any individuals attending a session for all claims which may arise out of the use of the techniques demonstrated or discussed therein . . . Some drugs or medical devices demonstrated in Powderz, Inc., courses or described in print or electronic publications have not been cleared by the FDA or have been cleared by the FDA for specific uses only. The FDA has stated that it is the responsibility of the physician to determine the FDA clearance status of each drug or device he or she wishes to use in clinical practice.”

e. Copies of materials for a presentation by The Cosmetic Pharmacy, for a September 18, 2004 seminar labeled “Hands-On Mesotherapy and Cosmetic Techniques Advanced Course.”<sup>7</sup> Dr. Zahra Karim, NMD is one of three individuals listed on the first page as an instructor. The materials include a section titled, “Botulinum Toxin Type A” and stated, “Botulinum Toxin Type A was recently approved for cosmetic use to soften the effects of stress, pollution and aging. It is simply another weapon in our arsenal to significantly enhance a person’s appearance thereby boosting their self-image, confidence, satisfaction, & enjoyment of life.” There is no mention of

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<sup>7</sup>Dr. Livdahl is the statutory agent of record for The Cosmetic Pharmacy. Aside from a varying suite number, The Cosmetic Pharmacy’s principal place of business is the same as TRI’s and Powderz’ – 3280 E. Hemisphere Loop, Tucson, Arizona, 85706. (Affidavit, ¶ 6).

BOTOX® or BOTOX® COSMETIC as the only FDA-approved drug derivations of Botulinum Toxin Type A. Several pages with instructions and diagrams for properly injecting the toxin into humans follow. Details as to the amount of units and the amount of injections recommended for each site on the human body are included. Injection points for the upper brow, medial brow, the forehead, area surrounding the eyes (crow's feet), below the eyes, mouth area, chin, and neck are all diagramed and explained. (Affidavit, ¶ 16, a-e).

During the search of TRI's offices, OCI agents also recovered the following records and documents:

a. A folder labeled "TRI Calls" which contained numerous handwritten notes reflecting names and telephone numbers of physicians throughout the United States. A number of these contacts were accompanied by handwritten notes indicating this contact information applied to doctors and facilities involved in plastic surgery, dermatology, and laser treatments. Also included in the folder was a printout of a testimonial from TRI's website by a Dr. Robert Baker, M.D., which included TRI's posted prices of the Botulinum Toxin Type A; specifically, one vial for \$1,250 and two vials for \$1,000. Handwritten notes on this printout state: "Botox for your wrinkles."

b. A typewritten contact list which contained the names, telephone numbers, addresses and handwritten facsimile numbers of physicians, many of whom are described as ophthalmologists, general surgeons, plastic surgeons and dermatologists.

c. An e-mail from Marina Stengart, Registered Nurse, to info@toxinresearch.com, stating her interest in purchasing a vial of TRI's product, asking for a recommendation for the dilution of

units per cc and how many milliliters one vial can hold. TRI responds that they will fax Nurse Stengart information on the product, including “how to reconstitute it, and other info.”

d. A TRI facsimile transmittal sheet, dated February 24, 2004, and addressed to Anita in Dr. Antall’s office from Susan at TRI, which states in part: “We received a call from you today about wanting to return our product due to you not noticing that our product is NOT meant for human use. . . . We have clearly marked everywhere you look on our product, website and printed material that it is a research product. We must state that for legal purposes to protect ourselves. Our product is simply Botulinum Toxin Type A which is exactly the same as any Botulinum Toxin Type A that you used in the past. . . . We hope you find some use for our product, and again we apologize but all sales are final.”

e. Stamped postcards addressed to various physicians advertising “A Very Stable Clostridium Botulinum Toxin Type A” and, in smaller print, the words “For Research Purposes Only Not For Human Use.” The postcard also sets forth prices of \$1,250 for one 500-IU vial and \$1,000 for two 500-IU vials, and provides a coupon offering “\$100 OFF your next Purchase.”

f. A printed copy of an electronic message from “clivdahl” to “Shannon@powderz.com”, dated December 10, 2003, asking Shannon to question the Center for Drug Evaluation and Research (“CDER”) of the FDA whether “we can apply for a generic even though our product does not have the same units as botox (we have 500 per vial and botox has 100), but each unit is equivalent, and we will be submitting studies to demonstrate that 1 unit of their [sp] is equal to 1 unit of ours. . . . Thanks, CHad.” (sic).

Furthermore, during the service of the search warrant at the offices of TRI on December 4, 2004, OCI special agents imaged the data contained within the computers located in the TRI

offices. OCI Special Agent Jay Scheurer, a Seized Computer Evidence Recovery Specialist, analyzed the data imaged from the TRI computers and determined that, on or about December 1, 2004, a person or person(s) at TRI attempted to delete computer records reflecting the sales of Botulinum Toxin Type A by TRI. Special Agent Scheurer succeeded in retrieving this data, which reflects invoices documenting sales of the Botulinum Toxin Type A within the Southern District of Florida to 13 customers, amounting to 33 invoices, for a total of \$53,211.15 (Affidavit, ¶ 23).

Additionally, aside from brochures, documents, records, and the like, physician testimonials demonstrate that TRI, Powderz, The Cosmetic Pharmacy, and in-turn, Livdahl and Karim intended their Botulinum Toxin Type A to be used on humans to affect their wrinkles. Dr. Martin Blau, a plastic surgeon, was told by TRI that hundreds of physicians were using its product. (Affidavit, ¶20). Dr. Herve Gentile ordered four vials from TRI. He was never told by TRI that they were not for human use. (Affidavit, ¶ 21).

Other physicians attended the seminars presented by Powderz. Dr. Santos Soberon attended a cosmetic workshop on July 19-20, 2003, presented by Powderz. Volunteers were injected with the purported “Botox” for wrinkle treatments by Dr. Robert Baker, and Dr. Bach McComb injected volunteers with Hyaluronic Acid. Dr. Soberon’s nurse, Patrise Heiman, who also attended, stated that during the workshop, Dr. Baker made it a point never to use the word “patients,” as though he was avoiding it; instead, Dr. Baker used the words, “when you inject your specimens.” Heiman stated it was as though Dr. Baker was making it a joke, as if to say, we are not supposed to be using the experimental Botox to inject people, but we’ll just keep it to ourselves. (Affidavit, ¶ 22a)

Dr. Martha Wilson attended the July 2003 conference, and states that all the attendees were told by the owners of Powderz that they could buy the toxin from them as a substantially lower price that Allergan was selling – approximately half the price. Dr. Wilson also stated she received an injection at the workshop. (Affidavit, ¶ 22b). Dr. James Lowry attended the same conference, and recalled viewing ‘how to’ slides on how to do the injections on humans. (Affidavit, ¶ 22c).

Dr. Felipe Jimenez witnessed two or three people get injected at the same seminar with a substance specified as Botulinum Toxin Type A. Dr. Jimenez said it was emphasized at the seminar that the Botulinum was for research purposes only. (Affidavit, ¶22d). Dr. Ann Murray was injected by a nurse at this seminar. She believed it was Botulinum Toxin Type A because it was “Chad’s Product.” (Affidavit, ¶22e). Dr. William Stephen Martin, witnessed some seminar participants receive injections of Botulinum Toxin Type A, and states that during the workshop it was mentioned that TRI manufactured the Botulinum Toxin Type A, and that it could be purchased for less than the Allergan BOTOX® [COSMETIC]. (Affidavit, ¶22f). Dr. Helen Donatelli said Doctors Karim and Livdahl were the speakers at this July 2003 seminar. Dr. Donatelli states the attendees were told that Livdahl and Karim’s product was more potent than BOTOX® [COSMETIC]. (Affidavit, ¶22g). And finally, Dr. Anya Landeck, who also attended the July 2003 conference, witnesses two medical doctors inject patient’s with TRI’s product, Botulinum Toxin Type A. Dr. Landeck reviewed the label of TRI’s product when talking to an FDA/OCI Agent, and said there were no directions for use, and the label only contained the company name of TRI, and the words, “for research purposes only, not for human use.” (Affidavit, ¶ 22h).

Further, in the course of conducting the search at the offices of TRI on December 4, 2004, OCI agents located documents concerning an entity called Z Spa, Inc. Records of the Arizona Corporation Commission reflect that Z Spa, Inc. (“Z-Spa”) was incorporated on February 13, 2004, and maintains its offices at 3280 E. Hemisphere Loop, Suite 116-E, Tucson, Arizona, the same suite of offices in which TRI and Powderz are located. The statutory agent listed in the corporate documents filed with the Arizona Corporation Commission is Chad Livdahl. (Affidavit, ¶ 24).

Among the documents recovered at the search of TRI was a fax from Vern Holmquist, which purports to pertain to “Zspa, Inc,” and accompanies a one page document which appears to be a proposed endorsement to an insurance policy. At the top of the page are the words, “AMENDATORY EXCLUSION – BOTOX.” On February 14, 2004, Agent Leeds telephoned Mr. Holmquist, who told Agent Leeds he is President of Pinnacle Insurance Agency, Inc., Scottsdale, Arizona, and has written insurance policies for Powderz. He stated he discussed Z Spa with Livdahl and Karim in May 2004, and then heard nothing more until approximately two weeks prior to Agent Leeds’ conversation with him, when he said the doctors called and said they were about ready to go with Z Spa. He faxed the endorsement to them at that time. Mr. Holmquist said he understood Botox treatments would be provided at Z Spa. (Affidavit, ¶ 25).

Also located during the search of TRI’s offices was a fax from Almond A D G, Inc. (“Almond”), Scottsdale, Arizona, to TRI and addressed to the attention of Chad Livdahl and Zahra Karim. Attached to the coversheet was an invoice in the amount of \$3,500.00 from Almond to TRI, dated December 1, 2004 and stamped “PAID.” The description of services rendered states: “Payment in full for the design and construction documents phase of the project

per the contract dated 12-1-04.” Attached to the invoice is a letter from Almond to Livdahl and Karim, dated December 1, 2004. The first sentence of the letter states: “The following is a proposal to provide Architectural/Engineering Services of a Tenant Improvement for ‘Z’ Spa proposed at Gainey Village, Scottsdale, Arizona.” Under the heading, “SCOPE OF PROJECT,” the letter states: “Convert a Cold Stone Creamery space into approximately 1,200 square feet for treatment rooms, consult, reception, administrative areas, and (1) restroom. Interior work only. No exterior improvements.” (Affidavit, ¶ 26)

On December 18, 2004 Agent Leeds reviewed the Internet website of Z-Spa, located at [www.z-spa.net](http://www.z-spa.net). The website states that Z Spa is currently located at 4380 N. Campbell Avenue, Suite 201 (no city provided), and further states: “Coming Soon: Z-Spa at Scottsdale Gainey Village.” On its website, Z Spa purports to have “the most advanced Anti-aging Skin Care Treatments available . . .”, and lists “Botox®” and “Restylane® & Collagen.” The website also publicizes an “Open House” at Z Spa scheduled for January 15 and 16, 2005, at the N. Campbell Avenue location, where, according to the website, patrons can expect “Free Education on the latest cosmetic treatments available.” (Affidavit, ¶ 27).

On December 20, 2004, Agent Leeds reviewed TRI’s website at [www.toxinresearch.com](http://www.toxinresearch.com). The web-site was still up and running, and the link to the Order Form was still operational. Also, on December 20, 2004, Agent Leeds placed a telephone call to the toll-free number listed on the TRI order form. A female voice on an answering machine identified the number that Agent Leeds dialed as that of “Toxin Research International,” and stated that Agent Leeds could dial the extension of the person to whom she wanted to speak if

she knew it, and if not, invited Agent Leeds to leave a message in the general mailbox.

(Affidavit, ¶ 28).

In addition, on December 14, 2004, FDA Special Agent Tina Stasulli Korb contacted by telephone Anita D'Entremont, head registered nurse at Hudson Dermatology, Neera Agarwal-Antal, MD Inc., located at 1325 Corporate Drive, Suite A, Hudson, Ohio 44235. (Affidavit 2, ¶¶ 1,2). Dr. Agarwal-Antal is a board-certified dermatologist and dermatologic surgeon.

D'Entremont advised Agent Korb Dr. Agarwal-Antal's office had received a flyer in the mail from TRI, advertising Botulinum Neurotoxin Type A for sale. The office ordered one vial, but upon seeing the label stating that it was not for human use, D'Entremont contacted TRI and advised them that she worked for a physician who did not do research. TRI would not take the product back. Dr. Agarwal-Antal's office then discarded the product. Following this incident, Dr. Agarwal-Antal's office continued to receive flyers from TRI advertising the Botulinum Toxin Type A and threw the flyers in the trash. (Id.)

On December 23, 2004, Agent Korb received a facsimile from D'Entremont forwarding a facsimile that Dr. Agarwal-Antal's office had received from TRI, dated 12/22/04 (facsimile attached as Exhibit 1 to Agent Korb's Affidavit). This fax markets Botulinum Toxin Type A to physicians. As evidenced by Dr. Agarwal-Antal's receipt of this facsimile after telling TRI that they are not engaged in research, it is clear that TRI continues to market its non-FDA-approved Botulinum Neurotoxin Type A to physicians.

The Supreme Court in United States v. Park, 421 U.S. 658, 672 stated that the FDCA:

. . . imposes not only a positive duty to seek out and remedy violations when they occur but also, and primarily, a duty to implement measures that will insure that violations will not occur. The requirements of foresight and vigilance imposed on responsible corporate

agents are beyond question demanding, and perhaps onerous, but they are no more stringent than the public has a right to expect of those who voluntarily assume positions of authority in business enterprises whose services and products affect the health and well-being of the public that supports them.

Given all of the foregoing evidence, it is abundantly clear that the defendants have run far far astray of the Supreme Court's edict in Park. It is unquestionable that the Botulinum Toxin Type A which defendants are marketing, promoting, educating people on, and selling in interstate commerce is a mislabeled drug within the meaning of the FDCA. Seminars were held to teach people how to inject their product. Brochures, syllabuses, and slides explaining the techniques for human injections were distributed and shown. Actual injections are demonstrated for the attendees, all the while mocking the fact of being able to avoid FDA regulations by simply using the proper terminology, "Not for human use. For Research only." Similar mockery is found in other correspondence. Further, strict warnings are given at these seminars prohibiting any type of video or audio recording at these seminars. Defendants affirmatively offered to beat the price of BOTOX® COSMETIC to prospective customers. Contact lists and handwritten notes reflect solicitation to ophthalmologists, general surgeons, plastic surgeons, and dermatologists. Computer records of TRI's client lists were purposefully deleted (and later recovered by FDA). Moreover, defendants have plans to open up a treatment center for anti-aging skin care, TRI's web-site and phone lines continue to be in operation, and they continue to market their product in interstate commerce.

The defendants' obvious sole purpose was to sell an alternative wrinkle treatment to the only FDA approved drug, derived from Botulinum Toxin Type A, BOTOX® [COSMETIC]. Such blatant intent for use, on humans while using a label stating, "Not for human use," under 21

C.F.R. 201.128, constitutes a misbranding of a drug, within the meaning of the FDCA, and thus, defendants should be enjoined from their false, deceptive, illegal, and most importantly, dangerous practices. \_\_\_\_\_

#### **IV. Defendants Have Violated the Fraud Injunction Statute, 18 U.S.C. § 1345**

18 U.S.C. § 1345, Injunctions Against Fraud reads, that: “(a)(1) If a person is –  
(A) violating or about to violate this chapter or sections 287, 371 (insofar as such violation involves a conspiracy to defraud the United States or any agency thereof), or 1001 of this title;. . . the Attorney General may commence a civil action in any Federal court to enjoin such violation.”  
When the FDA went to TRI to investigate in October of 2004, defendants Livdahl and Karim falsely represented to the FDA that they only sold their product only to research institutions and to licensed physicians conducting research, and they had no specific knowledge of the uses TRI customers might find for the Botulinum Toxin Type A. (Affidavit, ¶ 14). Defendants’ business records, including seminars records, sales records, and marketing lists, readily demonstrate the falsity of these statements at the time they were made. (Affidavit ¶¶ 7, 16, 17). Moreover, defendants continued to knowingly and wilfully to violate the law after FDA’s inspection in October 2004. TRI records show that as of December 1 and 2, 2004 TRI continued to sell its Botulism Toxin Type A to physicians engaged solely in the treatment of humans. (Affidavit, ¶ 17g). Further, defendants continued in their plans in December 2004 to open Z Spa, an anti-aging treatment center. (Affidavit, ¶¶ 26, 27). Additionally, defendants’ deliberate deletion of records reflecting sales to physicians not engaged in research provides additional evidence of their violations of 18 U.S.C. § 371 and 1001. (Affidavit, ¶ 23). Finally, TRI’s December 22, 2004, fax to its clients falsely claiming that it has cooperated fully with the FDA, and further,

continuing to market its non-FDA-approved Botulinum Neurotoxin Type A to physicians not engaged in research (Korb Affidavit, ¶¶ 2-3), is also significant. Because defendants have violated both Sections 371 and 1001, they have subjected themselves to the injunctive power of the Court under § 1345.

**A. Conspiracy to Commit Offense or to Defraud United States - 18 U.S.C.**

**§ 371**

Title 18, United States Code, Section 371 reads: “If two or more persons conspire either to commit any offense against the United States, or to defraud the United States or any agency thereof in any manner or for any purpose, and one or more of such persons do any act to effect the object of the conspiracy, each shall be fined under this title or imprisoned not more than five years, or both. . .” See U.S. v. Kimball, 291 F.3d 726, 733 (11<sup>th</sup> Cir. 2002) (violation of the FDCA is a fraud on the government); U.S. v. Bradshaw, 840 F.2d 871, 874 (11<sup>th</sup> Cir. 1988); U.S. v. Mitcheltree, 940 F.2d 1329, 1350-51 (10<sup>th</sup> Cir. 1991) (“intent to defraud or mislead” can be established by showing that the defendant took actions to avoid detection by the FDA); U.S. v. Cambra, 933 F.2d 752, 755 (9<sup>th</sup> Cir. 1991) (“intent to defraud of mislead” can be established by showing that the defendant “was trying to hide his activities from the FDA because he was worried that they certainly wouldn’t approve of what he was doing”).

Using the Eleventh Circuit Criminal Pattern Jury Instructions, as approved by the Court in United States v. Horton, 646 F.2d 181, 186 (5<sup>th</sup> Cir. 1981) the first element requires: That two or more persons, in some way or manner, came to a mutual understanding to try to accomplish a common and unlawful plan. Here, it is unquestionable that two or more persons came to a mutual understanding to try to accomplish a common and unlawful plan. As demonstrated by the

abundance of evidence above contained within Agent Leeds' affidavit, defendants Livdahl and Karim, through their entities of TRI, Powderz, and The Cosmetic Pharmacy, had a mutual understanding that they were going to market unregulated, unlicensed Botulinum Toxin Type A, as a drug for humans, and conceal that plan from the FDA. Furthermore, as evidence by Bach McComb's attendance as a seminar instruction at the Arizona Powderz' conference in July 2003, and the fact that Advanced Integrated, the clinic where Bach McComb worked out of, had ordered to the Botulinum Toxin Type A from TRI, it is clear that Livdahl and Karim also had a mutual understanding with Bach McComb.

The second element is that the defendant, knowing the unlawful purpose of the plan, willfully joined in it. By misrepresenting the true intent of their business to FDA Inspectors, defendants Livdahl, Karim and the entities they control to accomplish the unlawful distribution of the Botulinum Toxin Type A willfully joined in the unlawful purpose of marketing Botulinum Toxin Type A for human non-research use, and concealing their plan from the FDA, willfully attempted to defraud federal investigators when TRI was inspected in October 2004.

The third element requires that the conspirators during the existence of the conspiracy, knowingly committed one of the methods (or "overt acts") described. Again, amongst others the overt acts included lying to FDA inspectors and placing labeling on the Botulinum Toxin Type A stating "Not for human use. Research purposes only." Defendants knew they were marketing, shipping, and planning to ship their product for use on humans to treat wrinkles.

The fourth element is that such "overt acts" were knowingly committed at or about the time alleged in an effort to carry out or accomplish some object of the conspiracy. The labeling on the Botulinum Toxin Type A establishes their knowledge that it was not for use on humans.

Moreover, defendants lied to investigators in October 2004. During the search of TRI's offices, invoices dated December 1 and 2, 2004, were found, as well as completed order forms for TRI's Botulinum Neurotoxin Type A reflecting sales to: Richard Allen, whose order form includes a copy of a physician's assistant license in his name; Dr. Robert West at the Almos Heights Skin Clinic in San Antonio, Texas; Dr. Martha Gonzalez, Physician and Surgeon, Ventura, California; Dr. Kreg Jensen, Physician and Surgeon, Orem, Utah; and Dr. Herbert Smyczek, Newark, New Jersey. None of these physicians have indicated that they are involved in research. In fact, Dr. West's application specifically states that he is a member of a skin clinic. Further, defendants continued in their plans in December 2004 to open Z Spa, an anti-aging treatment center. (Affidavit, ¶¶ 26, 27). Thus, because defendants have violated 18 U.S.C. § 371, they should be enjoined from any further practices under 18 U.S.C. § 1345.

**B. False Statements to Federal Agency - 18 U.S.C. § 1001**

\_\_\_ Title 18, United States Code, Section 1001 reads: . . . “[W]hoever, in any matter within the jurisdiction of the executive, legislative, or judicial branch of the Government of the United States, knowingly and willfully – (2) makes any materially false, fictitious, or fraudulent statements or representation; shall be fined under this title or imprisoned not more than 5 years or both. 18 U.S.C. § 1001 thus makes it a federal crime or offense for anyone to willfully make a false or fraudulent statement to a department or agency of the United States. See Eleventh Circuit Criminal Pattern Jury Instruction.

The first element is that the defendant made the statement as charged. As Agent Leeds' has sworn to, upon her review of the FDA OCI Establishment Inspection Report, defendants Livdahl and Karim told OCI Johnson that the Botulinum Toxin is sold only to research institutions and to

licensed physicians conducting research. Dr. Livdahl also stated he did not know whether the researchers were injecting the product after reconstitution, and that he has no specific knowledge of the uses TRI customers might find for the Botulinum Toxin Type A. (Affidavit, ¶ 14).

The second element is that the statement was false. There can be no question here that this element is met. Defendants were conducting and giving instruction on how to inject their product into human beings. They were also soliciting their product to non-research physicians for use as an alternative to BOTOX® COSMETIC. (Affidavit, ¶¶ 16, 17, 22).

The third element is that the falsity related to a material matter. The test for determining materiality of a false statement knowingly and willfully made to an agency of the United States is “whether the statement has capability of affecting or influencing exercise of government function.” U.S. v. Herring, 916 F.2d 1543, 1547 (11<sup>th</sup> Cir. 1990). “The government must prove that the statement had the capacity to influence a determination required to be made in the course of the exercise of a governmental function.” U.S. v. Grizzle, 933 F.2d 943, 948 (11<sup>th</sup> Cir. 1991). The sale of the Botulinum Toxin Type A for human use is material, as defendants’ lengthy efforts to avoid detection show they were well aware of the FDCA’s parameters. If the product is sold for human use, it is a “drug” and the provisions of the FDCA apply. If defendants had been forthright with the FDA Inspectors, the enforcement and regulatory provisions of the FDCA would have kicked in. Therefore, by attempting to avoid FDA detection, the defendants have affected a government function, which is to approve drugs before they are used on humans. Consequently, defendants’ misrepresentations and omissions clearly related to a material matter.

Fourth is that the defendant acted willfully and with knowledge of the falsity. Again, defendants knew the use of their product, and defendants were actively seeking customers to use

their product on human beings.

Fifth, the false statement must have been made or used in relation to a matter within the jurisdiction of a department or agency of the United States. Under 21 U.S.C. § 371, the Secretary of Health and Human Services has the authority to promulgate regulations for the efficient enforcement of the FDCA. Moreover, under the FDCA, the FDA is charged with, and given the responsibility for monitoring and enforcing compliance. 21 U.S.C. § 374.<sup>8</sup> Hence, all the prerequisites have been met to show defendants have violated 18 U.S.C. § 1001; thus injunctive relief under 18 U.S.C. § 1845 is warranted.

## **V. Conclusion**

\_\_\_\_Defendants' practices warrant immediate and permanent injunctive relief. The potential for danger to the public is too great to allow defendants to continue to ship their product in interstate commerce, and to mislead individuals into thinking their product is one approved by the FDA, or that it is safe for human use. Further, defendants have committed a fraud on the United States

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<sup>8</sup>Additionally, as described in detail, *supra.*, the FDA has jurisdiction because defendants are in violation of 21 U.S.C. §332(a) in that they have delivered a misbranded drug in interstate commerce, as defined in 21 U.S.C. §§ 321(g) and 352(f).

government. Therefore, for the foregoing reasons, the United States respectfully requests this Court to order injunctive relief to stop defendants' illegal and harmful activities.

Respectfully submitted,

MARCOS DANIEL JIMENEZ  
UNITED STATES ATTORNEY

By: \_\_\_\_\_  
RUSSELL KOONIN  
Assistant United States Attorney  
Fla. Bar No. 0474479  
99 N.E. 4th Street, Suite 300  
Miami, FL 33132-2111  
Tel. No.: (305) 961-9314  
Fax No.: (305) 530-7139